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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,482	02/07/2002	Zairen Sun	1U 102 R1	7159

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,482	SUN ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 10-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>11/23/05</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> . |

DETAILED ACTION

RE: Sun et al

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/2005 has been entered.
2. Claims 1-27 are pending, claims 1-5 and 10-27 are withdrawn from further consideration as being drawn to non-elected subject matter.
3. Claims 6-9 are examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 8-9 under 35 USC § 112, 1st paragraph for new matter is maintained for the reasons of record. Applicant argues that the amended subject matter (i.e. the sequence of CDLFIQ) is supported by the instant specification as filed. Specifically, applicant relies on the disclosure on page 4, lines 16-17, wherein the specification indicates that the instant protein of SEQ ID No: 2 comprises an insertion of six amino acids that is lacking from a homologous sequence (i.e. AF326966). Applicant also points to figure 1, which applicant further indicates as support for the 6 amino acid

sequence. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The specification teaches the polypeptide sequence of ANH401 (SEQ ID No: 2) and further contemplates the sequences that are 98% and 99% identical to said ANH401 (see page 25, lines 13-15, for example). However, what the specification lacks is a specific recitation, either explicitly or implicitly, of a sequence that is 99% identical to ANH401 polypeptide (SEQ ID No: 2) comprising the sequence of CDLFIQ as claimed. No indication is provided in the specification or in the drawings, such that a sequence that is 99% identical to SEQ ID No: 2 contain that particular sequence (i.e. CDLFIQ).

Therefore the rejection of claims under 35 USC 112, 1st paragraph as new matter is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 8 and now newly rejected claims 7 and 9 under 35 USC § 112, 1st paragraph as lacking written description is maintained for the reasons of record. Applicant argues that the instantly amended claims, which recite hybridization language overcomes the instant rejection. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The amendment of the claims to indicate hybridization language, do not overcome the instant rejection. In particular, the claims are drawn to a polypeptide, it is unclear how hybridization language could be applied to polypeptides. Therefore the rejection is maintained.

Claims 8 and 9 are newly rejected because the specification does not support an isolated ANH401 polypeptide comprising an amino acid sequence having 99% identity to SEQ ID No: 2. The specification on page 25, for example, teaches that the ANH401 peptide as being SEQ ID No: 2 and does not include sequences that are anything other than SEQ ID No: 2. Therefore, an isolated human ANH401 polypeptide can only be SEQ ID No: 2 and therefore the genus of sequences that are encompassed by the claims reciting sequences that are 99% identical to SEQ ID No: 2 is not supported in the specification as filed. Applicant has not provided a sufficient number of sequences that are representative of the genus of sequences claimed. In addition, claim 7 as written broadly encompasses peptides (i.e. peptides which comprise 271-308 of SEQ ID No: 2) which are capable of binding to or specific for an ANH401 protein of SEQ ID No: 2. These encompass proteins and ligands that are capable of interacting with the ANH401 polypeptide of SEQ ID No: 2. The specification as filed has not provided one of skill in the art with any written support for sequences which are capable of binding to SEQ ID No: 2 as claimed. Moreover, the genus of sequences encompassed by the claim is broad and one of skill in the art would not know that applicant was in possession of the full scope of sequences given the disclosure as originally filed.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that

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[he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

New Arguments

Claim Rejections - 35 USC § 112, 2nd paragraph

6. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claim 8 has been newly amended to indicate hybridization language, wherein the polypeptide of SEQ ID No: 2 is capable of hybridizing under stringent conditions to the complement of SEQ ID No: 1. It is unclear as to how this hybridization is to occur, because it appears to go against the basic tenets of molecular biology.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claim 8, in particular has been amended to recite a polypeptide comprising an amino acid having 99% identity with SEQ ID No: 2 and which hybridizes to the complement of SEQ ID No: 1 under stringent conditions. The specification as filed does not support a polypeptide sequence that has the capability of hybridizing to a nucleotide sequence of SEQ ID No: 1 as claimed. Moreover, applicant has not specifically indicated, by page and line number, wherein in the specification such support can be found. Applicant is required to either specifically, point support in the specification or amend/cancel unsupported material.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Gandhi *et al* (WO2003000864A2). Gandhi *et al* teach a sequence that is 99% identical to that instantly claimed (see Exhibit A). Moreover, given that the sequence is 99% identical to SEQ ID No: 2, a nucleic acid which encodes SEQ ID No: 2 would, in the absence of evidence to the contrary, hybridize under stringent conditions as claimed. In addition, because the claimed sequence is 99% identical to the sequence as taught by Gandhi *et al* although not specifically taught as having dehydrogenase activity, given the degree of homology, the sequence as taught by Gandhi *et al* would have such claimed activity. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 1/14/05.

Conclusion

Claim 6 is allowed. Claims 7-9 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
November 14, 2005


CHRISTOPHER YAEN
PATENT EXAMINER